UNITED STATES PATENT AND TRADEMARK OFFICE

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In Re: Patent Term Extension
Application for
U.S. Patent No. 6,489,346

NOTICE OF FINAL DETERMINATION

An application for extension of the patent term of U.S. Patent No. 6,489,346 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on August 12, 2004. The application was filed by The Curators of the University of Missouri. Extension is sought based upon the premarket review under § 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a human drug product known by the tradename Zegerid™ having the active ingredients omeprazole and sodium bicarbonate. Zegerid™ (omeprazole and sodium bicarbonate) was approved for commercial use and sale by the Food and Drug Administration (FDA) on June 15, 2004

A determination has been made that U.S. Patent No. 6,489,346 is **NOT** eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of Zegerid® (omeprazole and sodium bicarbonate).

A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response **may** be extended pursuant to 37 CFR 1.136. See 37 CFR 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

As indicated in the application for patent term extension, and as supported by the Food and Drug Administration's web site, both omeprazole and sodium bicarbonate were previously approved for commercial use or sale. For example, on FDA's web site, the document "NDA Approvals for Calendar Year 2004" indicates that Zegerid™ is a new formulation, not that it contains a new active ingredient.

Under 35 U.S.C. § 156(a) a term of a patent which claims a product shall be extended if, *inter alia*, the product has been subject to a regulatory review period before its commercial marketing or use. In addition, under § 156(a)(5)(A):

> the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; (Emphasis added)

Thus, the determination of eligibility of U.S. Patent No. 6,489,346 turns on the provisions in § 156(a)(5)(A) that the permission for the commercial marketing or use is the first permitted commercial marketing or use of the product. The term "product" is defined in 35 U.S.C. § 156(f) as follows:

> (f) For purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (2) The term "drug product" means the active ingredient of -
> (A) A new drug, antibiotic drug, or human biological product...including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. (Emphasis added.)

A patent is only eligible for extension under 35 U.S.C. 156 if an active ingredient claimed by the patent and subject to regulatory review meets the "first commercial marketing" requirement of 35 U.S.C. 156(a)(5)(A). Omeprazole and sodium bicarbonate are separate active ingredients, and are not treated as a single active ingredient merely because they are administered together. Since the approval of Zegerid™ was not the first permitted marketing or use of either the active ingredient thereof, omeprazole and sodium bicarbonate, the patent is not eligible for patent term extension based upon the regulatory review of Zegerid™ (omeprazole and sodium bicarbonate). Arnold Partnership v. Dudas, 70 USPQ2d 1311 (Fed. Cir. 2004) (affirming a decision that U.S. Patent No. 4,587,252 is not entitled to patent term extension based upon the regulatory review and approval of hydrocodone bitartrate and ibuprofen, because both active ingredients had been previously approved for commercial use or sale).

As to applicant's argument that a showing of synergistic effect should have a bearing upon eligibility for patent term extension, applicant is considered to have established a synergistic effect between the two active ingredients. However, the court in Arnold noted:

> This court also addresses briefly whether synergistic combination drug patents qualify for a patent term extension under § 156...Moreover, this court doubts that synergistic effects are an appropriate distinction for term extension policies, particularly where the statutory language does not distinguish at all between synergistic and nonsynergistic combinations. Arnold at 1315.

In view of the Arnold decision, Section 2751 of the Manual of Patent Examining Procedure, Rev. 2, May 2004, will be revised to remove the suggestion that a synergistic effect could have a bearing upon whether a combination product could be considered a single active ingredient for purposes of 35 U.S.C. 156. (This is found in the paragraph spanning pages 2700-31 and 2700-32.)

In view of the above, the term of U.S. Patent No. 6,489,346 is not eligible for extension under 35 U.S.C. § 156 based upon the approval of the product Zegerid™ (omeprazole and sodium bicarbonate) and the application for patent term extension, filed August 12, 2004, is dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (703) 872-9411 (please contact the undersigned if sending a fax after September 28, 2004, the fax number may have changed)

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159. (After September 28, 2004, the telephone number should be (571)272-7744.) E-mail inquiries should be directed to Karin.Ferriter@uspto.gov.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

Attachment: NDA Approvals for Calendar Year 2004 (Updated through July 31 2004)

NDA APPROVALS FOR CALENDAR YEAR 2004

Updated through July 31, 2004

NDA Number	Drug Name	Generic Name	Applicant/ Sponsor	Chemical Type	Therapeutic Class	Approval Date
21604	Children's Elixsure IB	Ibuprofen	Taro Pharms	5	S	07-Jan-04
21539	Acetadote	Acetylcysteine	Cumberland Pharms	3	PV	23-Jan-04
21646	Infuvite Pediatric	Multiple Vitamins	Sabex 2002	5	S	29-Jan-04
21395	Spiriva Handihaler	Tiotropium Bromide	Boehringer Ingelheim	1	S	30-Jan-04
21540	Caduet	Amlodipine Besylate;Atrovastatin Calcium	Pfizer	4	S	30-Jan-04
21625	MVI Adult	Multi-Vitamins	aaiPharma	3	S	30-Jan-04
21462	Alimta	Pemetrexed Disodium	Eli Lilly	1	PV	04-Feb-04
21594	Amiodarone Hydrochloride	Amiodarone Hydrochloride	International Medication Sys	5	S	04-Feb-04
21644	Clobex	Clobetasol Propionate	Galderma Labs	3	S	05-Feb-04
21166	Estrogel	Estradiol	Solvay Pharms	3	S	09-Feb-04
21590	Fazaclo	Clozapine	Alamo Pharms	3	S	10-Feb-04
21643	MVI Adult	Multi-Vitamins	aaiPharma	3	S	18-Feb-04
21587	Children's Advil Allergy Sinus	Ibuprofen;Pseudophedrine Hydrochloride;Chlorpheniramine Maleate	Wyeth Cons	3	S	24-Feb-04
50791	Myfortic	Mycophenolic Acid	Novartis Pharms	2	S	27-Feb-04
21571	Iquix	Levofloxacin	Santen	3	S	01-Mar-04
21688	Sensipar	Cinacalcet Hydrochloride	Amgen	1	P	08-Mar-04
21621	Zyrtec	Cetirizine Hydrochloride	Pfizer	3	S	16-Mar-04
21211	Follistim AQ	Follitropin Beta	Organon	3	S	23-Mar-04
21765	Gonal-F	Follitropin Alfa	Serono Inc	3	S	25-Mar-04
21253	Zyprexa IM	Olanzapine	Eli Lilly	3	S	29-Mar-04
21144	Ketek	Telithromycin	Aventis Pharms	1	S	01-Apr-04
20784	Nasacort HFA	Triamcinolone Acetonide	Aventis Pharms	3	S	07-Apr-04

21256	Human Secretin	Human Secretin	Chirhoclin	1	PV	09-Apr-04
21629	Apidra	Insulin Glulisine	Aventis Pharms	1	S	16-Apr-04
21264	Apokyn	Apomorphine Hydrochloride	Bertek	1	P	20-Apr-04
21574	Fortamet	Metformin Hydrochloride	Andrx	5	S	27-Apr-04
21640	Vitrase	Ovine Hyaluronidase	Ista Pharms	1	P	05-May-04
21504	Lidosite Topical System	Lidocaine Hydrochloride; Epinephrine	Vyteris	3	S	06-May-04
21617	Zalkote	Valproate Sodium	Andrx	3	S	06-May-04
21443	Enjuvia	Synthetic Conjugated Estrogens, B	Duramed	3	S	10-May-04
21551	Halflytely and Bisacodyl Bowel Prep Kit	PEG-3350;Sodium Chloride;Sodium Bicarbonate;Potassium Chloride;Bisacodyl	Braintree	3	S	10-May-04
21433	Flovent HFA	Fluticasone Propionate	GlaxoSmithKline	3	S	14-May-04
21618	Tindamax	Tinidazole	Presutti Labs	1	SV	17-May-04
21671	Depodur	Morphine Sulfate	Skye Pharma	3	S	18-May-04
50794	Vidaza	Azacitidine	Pharmion	1	PV	19-May-04
21361	Xifaxan	Rifaximin	Salix Pharms	1	S	25-May-04
21494	Axid	Nizatidine	Reliant Pharma	3	S	25-May-04
21684	Gonal-F RFF Pen	Follitropin Alfa	Serono Inc	3	S	25-May-04
21566	Prevacid IV	Lansoprazole	Tap Pharm	3	S	27-May-04
21595	Sanctura	Trospium Chloride	Indevus	1	S	28-May-04
21530	Mobic	Meloxicam	Boehringer Ingelheim	3	S	01-Jun-04
21516	Istalol	Timolol Maleate	Senju	3	S	04-Jun-04
21667	NutreSore	L-Glutamine	Nutritional Restart	1	SV	10-Jun-04
21636	Zegerid	Omeprazole	Santarus	3	S	15-Jun-04
21369	Codeprex	Codeine Polistirex;Chlorpheniramine Polistirex	Celltech Pharms	3	S	21-Jun-04
21585	Mucinex D	Guaifenesin;Pseudoephedrine Hydrochloride	Adams	3	S	22-Jun-04
21512	Loratadine	Loratadine	Perrigo	3	S	24-Jun-04
50789	Tobramycin	Tobramycin	American Pharm	5	S	13-Jul-04
21612	Luxacor	Fenofibrate	Cipher	3	S	15-Jul-04
21497	Alinia	Nitazoxanide	Romark	3	P	21-Jul-04
21687	Vytorin	Ezetimibe; Simvastatin	MSP Singapore	4	S	23-Jul-04
21415	Metvix	Methyl Aminolevulinate	PhotoCure ASA	3	S	27-Jul-04
21431	Campral	Acamprosate Calcium	Lipha	1	P	29-Jul-04
	Cefotaxime and Dextrose					

50792	Duplex Container	Cefotaxime Sodium	B Braun	5	S	29-Jul-04

Chemical Types:
1 - New molecular entity
2 - New ester, new salt, or other noncovalent derivative
3 - New formulation
4 - New combination
5 - New manufacturer
6 - New indication (Beginning in 1994, Type 6's were tracked as efficacy supplements, not as NDAs.)
7 - Drug already marketed, but without an approved NDA

Therapeutic Potentials:
P - **Priority Review** - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease.
S - **Standard Review** - The drug appears to have therapeutic qualities similar to those of one or more already marketed drugs.
V - **Orphan Drug**

Back to Top Reports

Date created: March 5, 2004; updated August 16, 2004